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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,685	SHACHAR, YEHOSHUA	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-39 and 41-64* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-16,18,20-25,28-30,32,33,37-39,41-43,47,51,55-57 and 62-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7, 8, 17,19,20,23,26,27,31,34-36,44-46,48-50,52-54 and 58-61.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/2007 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 7/10/2007.

3. In the reply, the Applicant amended claims 1, 3-5, 33 and cancelled claim 2.

Election/Restrictions

4. The Applicant additionally argued for reconsideration of the Restriction and Withdrawal of Claims (Remarks, pg 14). The Examiner notes that at no point during prosecution did the Applicant elect Apparatus Species III. The claim of misnaming the elected species is not persuasive after the fact. The election without traverse of the Apparatus Species stands as Species II.

5. Further, the Examiner notes that the deconstruction of the claims into Species II and III centers on the control systems – whether the regulation of agent administration is perform autonomously via sensors or actively controlled by an external user. In this regard, the type of pump is generic (see additional discussion below in Claims Rejections –35 USC 112).

6. Finally, upon reconsideration of the withdrawal of claims the Examiner finds claims 1, 3-6, 9-16, 18, 20-25, 28-30, 32, 33, 37-39, 41-43, 47, 51, 55-57, 62-64 to read on the elected invention and are rejoined pursuant to MPEP 824.04 (claims drawn to type of agent administered are found to be generic); whereas claims 7, 8, 17, 19, 20, 23, 26, 27, 31, 34-36, 44-46, 48-50, 52-54, 58-61 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

7. Thus, claims 1, 3-6, 9-16, 18, 20-25, 28-30, 32, 33, 37-39, 41-43, 47, 51, 55-57, 62-64 are pending for examination.

The requirement is still deemed proper and is therefore made FINAL.

Specification

8. The use of the trademark "Integra" and "FortaPerm" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3, 4, 5, 8, 9, 10, 12, 22, 24, 25, 28-30, 37, 38, 41, 42 recites the limitation "the piezoelectric pumps" or "said piezoelectric pump". There is insufficient antecedent

basis for this limitation in the claim because claim 1 no longer recites "piezoelectric pump." The Examiner suggests modifying claim 1 to include the pump being piezoelectric.

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites a implantable pouch being a bioabsorbable material and multiple pumps being fabricated in the pouch which *forms the skeleton of the pumps*". Websters defines skeleton as "a usually rigid support structure". The Applicant's limitation claims that the skeleton of the pumps, that is - the physical structure of the pumps themselves, are formed of a bioabsorbable material. This is inconsistent with the pumps being a piezoelectric material – standard piezoelectric materials are not biodegradable. Appropriate correction is required. Furthermore, implantable control circuits are not made of bioabsorbable material either. The Examiner is unsure of how the Applicant's biodegrading pouch functions in conjunction with non-biodegradable device elements such as the piezoelectric valves and implanted control circuit. A degrading pouch would eventually degrade to the point where the device would cease to function – the chambers would no longer be capable of holding medicating agents, the piezoelectric elements and control circuitry would be exposed to the patient's body. It is not clear to the Examiner how the Applicant's may function in the body and to degrade in the body while device elements are not biodegradable. Appropriate clarification and correction is required.

12. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "an implanted circuit proximate to the pumps". However, the Applicant has failed to set a reference system to determine what proximate to the pumps means. Neither of the implantable pouch or pumps have proximate or distal ends. The Examiner is unclear as to what "proximate" means because of the lack of a reference in the device. Currently, "proximate to the pumps" is interpreted as being anywhere on the device because of the lack of reference frame. Appropriate correction is required.

13. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites the limitation "pouches" in ln 11. The Examiner believes the Applicant that there is only one singular implantable pouch and thus referring to multiple "pouches" in incorrect. Appropriate correction is required.

14. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites the limitation "to provide for controlled delivery of." The Examiner believes the Applicant is missing a phrase describing what is controllable delivered. Appropriate correction is required.

Claim Objections

15. Claims 7, 9, 12, 16, 18, 19, 23, 26, 29, 37, 38, 44, 48, 50, 53, 55, 59, 60, objected to because of the following informalities: Claims fail to have a period at the end of the claim. Appropriate correction is required.

16. Claim 37 is objected to because of the following informalities: Claim 37recites "claim 1, piezeoelectric pump". Appropriate correction is required.

17. Claim 55 is objected to because of the following informalities: Claim 55 recites "me"; wherein the limitation should read "be". Appropriate correction is required.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1, 3, 5, 6, 11-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 55, 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Soykan et al (6206914).

20. Soykan et al discloses an implantable apparatus comprising: an implantable pouch (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61) having multiple chambers composed of a bioabsorbable material and multiple medicating agents disposed in said chambers (col 4, lns 18-32; col 8, lns 56-67, col 9, lns 35-37; col 9, lns 38-59, col 12, lns 51-65; wherein each of the microscopic

containment vehicles forms a chamber and each of the containment vehicles is capable of containing various cells and therapeutic agents); multiple implantable piezoelectric pumps (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39) fabricated in the pouch which forms a skeleton of the pumps, the pumps being configured to transfer medicating agents to said patient (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39); and an implantable, biocompatible and bioabsorbable skin (col 9, lns 38-60, col 10, lns 4-col 11, lns 14) covering the pouch and pumps; and an implanted control circuit (col 4, lns 18-32, col 13, lns 16-27, col 14, lns 10-39, col 15, lns 4-24, col 16, lns 18-61) to control proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously as determined by locally sensed homeostatic parameters (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61; and discussion below in Response to Arguments).

21. In reference to claims 3, 5, 6, 11-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 55, 62-64 see (col 3, lns 6-31; col 5, lns 55-59; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61; discussion below in Response to Arguments; wherein the Examiner notes that the device of Soykan et al is fully capable of being placed in at a tumor cite and the sensing elements are fully capable of measuring pressure, temperature, pH, and various physiological properties that can be representative of the state of the tumor site to control agent release and furthermore the

drug-eluting cells may be genetically engineered to produce a variety of therapeutic agents (col 8, lns 19-27; additionally the Examiner notes that a pleiotrophic agent is merely an agent that produces many effects and Soykan et al discloses many agents that produce many effects in the body).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 4, 9, 10, 21, 30, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al in view of Humes et al (2002/0090388). Soykhan et al discoses the invention substantially as claimed except for expressly disclosing delivering cytokine, chemotherapeutic agents to eliminate tumors. Humes et al teaches that it is known to have a drug delivery device delivering cytokine, chemotherapeutic agents ([011], [074], [075]) for the purpose of tumor elimination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the agents as taught by Soykan with the cytokine and chemotherapeutic agents as taught by Humes et al for the purpose of delivering therapeutic agents for the purpose of tumor elimination.

Response to Arguments

24. Applicant's arguments with respect to claims 1-5, 33, and 40 have been considered but are moot in view of the new ground(s) of rejection.

25. The Applicant argues that Soykan et al does not disclose a) the control circuit to be implanted and proximate to the pump; b) the control circuit to control proper dosing and scheduling in a closed loop; and c) the control circuit operating autonomously as determined by local homeostatic parameters.

26. In response to the applicant's argument (a), the Examiner first notes that 'proximate to the pump' has no reference point (see 112 rejection) and thus is being considered as anywhere on the pump. Secondly, Soykan et al discloses an implanted control circuit (col 3, lns 12-30, col 13, lns 16-27, 47-col 14, lns 58; col 15, lns 5-12; col 17, lns 15-20). Wherein the stent and the sensor device may be separated as shown in Fig 2, or may be attached in a single device. Furthermore, the control circuitry for electrically stimulating the piezoelectric pump to stimulate release of the therapeutic agents from the multiple microscopic containment vehicles is located on the stent itself.

27. In response to the applicant's argument (b), the Examiner notes that Soykan et al discloses a control circuit to control proper dosing and scheduling in a closed loop (col 3, lns 12-30, col 13, lns 16-27, 47-col 14, lns 58; col 15, lns 5-12; col 17, lns 15-20). Wherein, the control circuitry controls the electrical stimulating elements that function to control the piezoelectric pump to stimulate release of the therapeutic agents from the multiple microscopic containment vehicles via direct feedback from sensing elements that detected physiological properties and determining from information from the sensing elements whether to trigger release of agents or cease release of agents.

28. In response to the applicant's argument (c), the Examiner notes that Soykan et al discloses the control circuit operating autonomously as determined by local homeostatic

parameters (col 3, lns 12-30, col 13, lns 16-27, 47-col 14, lns 58; col 15, lns 5-12; col 17, lns 15-20). The control circuitry controls the electrical stimulating elements that function to control the piezoelectric pump to stimulate release of the therapeutic agents from the multiple microscopic containment vehicles via direct feedback from sensing elements that detected physiological properties and determining from information from the sensing elements whether to trigger release of agents or cease release of agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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